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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/449,817	11/26/99	STEINER M	P-2762-US1

HM22/0928
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EXAMINER	
KERR, K	
ART UNIT	**PAPER NUMBER**
1652	23

DATE MAILED: 09/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/449,817	STEINER ET AL.	
	Examiner	Art Unit	
	Kathleen M Kerr	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *16 August 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7,10-27,30-36,40,44,45,47 and 54-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,7,10-27,30-36,40,44,45,47 and 54-60* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Application Status

1. In response to the previous Office action, a Notice to Comply with the Sequence Rules (Paper No. 19 mailed on July 5, 2001), Applicants filed a sequence response and preliminary amendment (Paper No. 21). Said preliminary amendment amended the claims.

2. Upon filing the amendment (Paper No. 21), it is clear that Applicants have not correctly recorded the pending claims in the instant application; the following is a record of the pending claims as has been filed with the Office.

a) On November 26, 1999, the application was originally filed with Claims 1-53.

b) In preliminary amendment A (Paper No. 8 filed on June 12, 2000), Applicants cancelled Claims 28, 29, 37-39, 41-43, 46, and 48-53; thus Claims 1-27, 30-36, 40, 44, 45, and 47 were pending.

c) In preliminary amendment B (Paper No. 16 filed on May 21, 2001), no claim amendments were made; thus Claims 1-27, 30-36, 40, 44, 45, and 47 were pending.

d) In preliminary amendment C (Paper No. 21 filed on August 16, 2001), Applicants cancelled Claims 2-6, 8, and 9 and added 7 new claims (incorrectly numbered 53-59). These new claims were renumbered appropriately (see Rule 126(a)) as Claims 54-60. Thus, Claims 1, 7, 10-27, 30-36, 40, 44, 45, 47, and 54-60 are pending in the instant application.

3. To reiterate, Claims 1, 7, 10-27, 30-36, 40, 44, 45, 47, and 54-60 are pending in the instant application.

Restriction

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1, 7, 10, 11, 18-27 and 54-60, drawn to nucleic acid sequences, vectors, and host cells, classified in class 435, subclass 325.

II. Claims 12-17, drawn to oligonucleotides and antisense DNA, classified in class 536, subclass 24.31.

III. Claims 30-32 and 35, drawn to polypeptides and pharmaceutical compositions thereof, classified in class 530, subclass 350.

IV. Claims 33-34, drawn to antibodies, classified in class 530, subclass 387.9.

V. Claim 36, drawn to transgenic animals, classified in class 800, subclass 8.

VI. Claim 40, drawn to methods of screening a tumor sample, classified in class 435, subclass 6.

VII. Claim 44, drawn to methods of inhibiting the growth of cancer cells, classified in class 424, subclass 93.21.

VIII. Claims 45 and 47, drawn to methods of suppressing the growth of cancer cells and methods of inducing susceptibility to apoptosis of cancer cells, classified in class 514, subclass 44.

5. The inventions are distinct, each from the other because of the following reasons:

Group I, drawn to nucleic acid sequences, and Group II, drawn to oligonucleotides and antisense molecules, are related by virtue of the complementarity of the nucleic acid sequences. However, these sequences have different linear structures and different functions. For example,

antisense polynucleotides are useful for gene therapies while the nucleic acid sequences are useful for the recombinant production of the encoded protein. Therefore, Groups I and II are patentably distinct. Moreover, a search burden is identified by virtue of not only the distinct sequences, but also the different class/subclass classifications which would require searching.

Group I, drawn to nucleic acid sequences, and Group III, drawn to polypeptides, are related by virtue of the fact that the DNA encode the polypeptides. The DNA molecule has utility for the recombinant production of the polypeptide in a host cell. Although the DNA and the polypeptide are related, they are distinct inventions because the polypeptide product can be made by other and materially distinct processes, such as purification from a natural source. Furthermore, DNA can be used for processes other than the production of polypeptide, such as nucleic acid hybridization assays. Therefore, Groups I and III are patentably distinct. Moreover, a search burden is identified by virtue of not only the distinct sequences (DNA vs. protein which requires searching is distinct databases), but also the different class/subclass classifications which would require searching.

Group I, drawn to nucleic acid sequences, and Group IV, drawn to antibodies, are related by virtue of the polypeptides that are encoded by the nucleic acid sequences and necessary for the production of the antibody. However, the DNA itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, Groups I and III are patentably distinct.

Group I, drawn to nucleic acid sequences, and Group V, drawn to transgenic animals, are related because the transgenic animals comprise at least one nucleic acid sequence from Group I. However, nucleic acids and transgenic animals are wholly different compounds having different

compositions and functions as evidenced by their distinct class/subclass classifications. Therefore, Groups I and V are patentably distinct.

Group I, drawn to nucleic acid sequences, and Groups VI-VIII, drawn to various methods, are related as and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the nucleic acid sequences can be used in a materially different process of using that product, for example, in the recombinant production of the encoded protein. Thus, Group I is patentably distinct from Groups VI-VIII. Moreover, the various class/subclass classifications identify a search burden for these groups to be searched together.

Group II, drawn to oligonucleotides, is unrelated to Groups III-VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case, the oligonucleotides are not disclosed as being used with the polypeptides, the antibodies, or the transgenic animals. Moreover, the oligonucleotides are not disclosed as being used in the methods of Groups VI-VIII. Thus, Group II is patentably distinct from each of Groups III-VIII.

The polypeptides of Group III and the antibodies of Group IV are related by virtue of being the cognate antigen (polypeptide) necessary for the production of the antibody. Although the polypeptide and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because they are functionally distinct chemical entities and because

the polypeptides can be used in processes materially distinct from the process to produce antibody, such as in a enzyme activity assays. Furthermore, the polypeptides can be made using other and materially distinct processes from those used to make an antibody; for example, the polypeptides can be made using organic synthesis while antibody production can be *in vivo*. Therefore, Groups III and IV are patentably distinct.

Group III, drawn to polypeptides, and Group V, drawn to transgenic animals, are related because the transgenic animals comprise at least one nucleic acid which encodes the polypeptides. However, polypeptides and transgenic animals are wholly different compounds having different compositions and functions as evidenced by their distinct class/subclass classifications. Therefore, Groups III and V are patentably distinct.

Group III, drawn to polypeptides, is unrelated to Groups VI-VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case, the polypeptides are not disclosed as being used in the methods of Groups VI-VIII, all these methods use nucleic acid sequences. Thus, Group III is patentably distinct from each of Groups VI-VIII.

The antibodies of Group IV and the transgenic animals of Group V are related by virtue of the polypeptide which is encoded by the nucleic acids comprised in the transgenic animals and which polypeptide is the cognate antigen necessary for the production of the antibodies. However, antibodies and transgenic animals are wholly different compounds having different compositions and functions as evidenced by their distinct class/subclass classifications. Therefore, Groups IV and V are patentably distinct.

Group IV, drawn to antibodies, is unrelated to Groups VI-VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case, the antibodies are not disclosed as being used in the methods of Groups VI-VIII, all these methods use nucleic acid sequences. Thus, Group IV is patentably distinct from each of Groups VI-VIII.

Group V, drawn to transgenic animals, is unrelated to Groups VI-VIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case, the transgenic animals are not disclosed as being used in the methods of Groups VI-VIII, all these methods use nucleic acid sequences. Thus, Group V is patentably distinct from each of Groups VI-VIII.

Groups VI-VIII are related as methods using the nucleic acid sequences of Group I. However, these methods are distinct because they use wholly different method steps and reagents to produce wholly different products. Thus, Groups VI-VIII are patentably distinct, each from the other.

Notice of Possible Rejoinder

6. The Examiner notes that if Group I is found directed to an allowable product, then Groups VI-VIII, which are directed to processes of using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. § 821.04, *In re* Ochiai, and *In re* Brouwer).

Election of Species

7. All Groups in this application contain claims directed to the following patentably distinct species of the claimed invention: human sequences SEQ ID NOs: 1 and 2 and rat sequences SEQ ID NOs: 3-6.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1, 7, 10-27, 30, 32-36, 40, 44, 45, 47 are generic as being drawn to mammalian p-Hyde.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

Election

8. A telephone call was made to Mr. Mark Cohen on September 27, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

Conclusion

9. Applicants must reply to the instant Office action with an election of a Group as listed above AND an election of species (human or rat) to which the claims will be limited if a generic claim is not determined to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

KMK
September 27, 2001